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TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371			U.S. APPLICATION NO. (if known, see 37 CFR 1.5) <b>10/031563</b>
INTERNATIONAL APPLICATION NO. PCT/FR00/02085	INTERNATIONAL FILING DATES 20 July 2000	PRIORITY DATE CLAIMED 22 July 1999	
TITLE OF INVENTION MULTIAXIAL CONNECTION FOR OSTEOSYNTHESIS			
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Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:			
<ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing 35 U.S.C. 371</li> <li>3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371 (f)). The submission must include items (5), (6), (9) and (21) indicated below.</li> <li>4. <input checked="" type="checkbox"/> The US has been elected by the expiration of 19 months from the priority date (PCT Article 31).</li> <li>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c)(2)) <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input checked="" type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</li> </ol> </li> <li>6. <input checked="" type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)). <ol style="list-style-type: none"> <li>a. <input checked="" type="checkbox"/> is attached hereto.</li> <li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</li> </ol> </li> <li>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)) <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input checked="" type="checkbox"/> have not been made and will not be made.</li> </ol> </li> <li>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).</li> <li>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). (Unexecuted)</li> <li>10. <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).</li> </ol>			
Items 11 to 20 below concern document(s) or information included:			
<ol style="list-style-type: none"> <li>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</li> <li>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</li> <li>13. <input type="checkbox"/> A FIRST preliminary amendment.</li> <li>14. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment.</li> <li>15. <input type="checkbox"/> A substitute specification.</li> <li>16. <input type="checkbox"/> A change of power of attorney and/or address letter.</li> <li>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.</li> <li>18. <input checked="" type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4).</li> <li>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</li> <li>20. <input checked="" type="checkbox"/> Other items or information: Copy of International Preliminary Examination Report (in French &amp; English) Four (4) Sheets of Formal Drawings, Copy of International Search Report</li> </ol>			

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## MULTIAXIAL CONNECTION FOR OSTEOSYNTHESIS

The present invention relates to a multiaxial connection osteosynthesis system, in particular for the spine.

In the context of surgery to the vertebral column, for example, and in particular using a posterior approach route, the surgeon is often confronted with the problems of misalignment of the anchor members and interference between anchor members on two adjacent vertebrae. This problem increases the operating time or prevents the surgeon from carrying out the desired procedure under the best possible conditions. The cause of this problem is that the coupling member between the member connecting the various vertebrae together and the anchor member implanted in the vertebra is rigidly connected to the anchor member.

Document WO 97/02786 discloses a multiaxial connection between the members. The anchor member has a hemispherical head. The coupling member includes, in addition to means for receiving the member connecting the various vertebrae together, a split chamber in its bottom part adapted to receive the hemispherical head. The external surface of the coupling member includes a cone that is flared toward the bottom end. A clamping collar can be threaded over the top portion of the coupling member to bear on the conical portion. Before tightening, the coupling member is free to rotate relative to the anchor member. Locking in position is effected when tightening the member connecting the vertebrae together, which bears on the clamping collar, which at the same time closes the receiving chamber on the hemispherical head of the anchor member.

The complexity of the positional locking mechanism, because of its large number of components, obliges the surgeon to carry out supplementary manipulations, and

consequently increases the operating time.

An object of the invention is to provide a multiaxial connecting device that is simple to use and requires only a small number of operations to fit it.

5 To achieve this object, the present invention provides a multiaxial connection osteosynthesis system, in particular for the spine, including a bone anchor member having a head, a connecting member, a connector having a first deformable housing adapted to receive the head and a  
10 second housing adapted to receive the connecting member, the system including clamping means for clamping the connecting member in the second housing. The connector is arranged so that, when the clamping means load the connecting member in the second housing, the connecting  
15 member loads the connectors directly to deform the first housing and immobilize the head therein.

Thus the first deformable housing is closed onto the head. This reduces the number of components and therefore simplifies the use of the device.

20 The first housing advantageously includes a chamber with a concave surface.

The concave surface chamber is advantageously complementary to all or part of the convex surface of the head.

25 The first housing advantageously includes a cavity adapted to receive part of the head.

The connector advantageously includes a slot in the first housing.

30 Thus the first housing can have a more pronounced elastic deformability while inserting the head and while locking of the device in position.

The head advantageously has a spherical part.

35 The first housing advantageously has a U-shaped opening having an axis and two branches at a distance from and facing each other.

The slot is advantageously perpendicular to the axis of the U-shaped opening.

The branches of the U-shaped opening advantageously have a screwthread.

5       The clamping means advantageously include a locking member adapted to engage between the branches of the U-shaped opening.

The clamping means advantageously include a flange adapted to fit around the branches of the U-shaped opening.

10       Accordingly, when clamping the nut, the flange prevents spreading of the branches of the U-shaped opening.

The screwthread advantageously has a face substantially perpendicular to the axis of the thread and oriented in a penetration direction of the clamping means on the connector.

15       Accordingly, during clamping, the face substantially perpendicular to the axis of the thread of the locking member comes into contact with the face of the branches of the U-shaped opening. The reaction force generated in this way is substantially parallel to the axis of the thread and this minimizes the radial reaction force, which would otherwise spread apart the branches of the U-shaped opening.

20       Other features and advantages of the invention will become more apparent in the course of the following description of three preferred embodiments, which description is given by way of non-limiting example. In the accompanying drawings:

- 25       - figure 1 is a partial perspective view of a first embodiment of the system;
- 30       - figure 2 is an exploded perspective view of the system shown in figure 1;
- figure 3 is a view of the system in section taken along the line III-III in figure 1;
- 35       - figure 4 is a top perspective view of a first

- embodiment of the connector;
- figure 5 is a bottom perspective view of the connector shown in figure 4;
  - figure 6 is a view of the connector in section taken along the line VI-VI in figure 4;
  - figure 6a is a diagrammatic sectional view of the Christmas tree thread of the connector shown in figure 4;
  - figure 7 is a bottom perspective view of a second embodiment of the connector; and
  - figure 8 is a bottom perspective view of a third embodiment of the connector.

A first embodiment of the invention is described with reference to figures 1 to 6a.

The osteosynthesis system includes at least two vertebral anchor members 2, connecting means 4, such as a rod, between the anchor members 2 and the other anchor members (not shown) of the osteosynthesis system, a connector 6 adapted to be fitted to the member 2, and a locking member 8 adapted to cooperate with the connector 6.

The vertebral anchor member 2, which here takes the form of a bone screw, has a circular section cylindrical threaded body 10 carrying a bone thread (not shown). The member also has a head 12 with a convex surface 14, here a surface of revolution whose axis coincides with the axis of the screw 16. The convex surface has a spherical lateral portion 18, a flat top portion 22 perpendicular to the axis of the screw, and a connecting fillet 20 between them. The head 12 includes means 24 for operating the screw 2, here in the form of a hexagonal socket 24.

Here the locking member is generally screw-shaped and has a thread 26 adapted to cooperate with the thread 28 on the connector 6, described hereinafter. The latter also includes operating means 30 in the form of a hexagonal socket 30.

The connector 6 provides a coupling member between the bone screw 2 and the connecting rod 4. The general shape of the coupling member is that of a circular section cylinder. It has a top portion 6a for connecting it to the rod 4 and a bottom portion 6b for connecting it to the bone screw 2.

The top portion 6a of the coupling member 6 includes a U-shaped opening 32 which has an axis 42 and is delimited by two facing branches 34 at a distance from each other. The two branches 34 constitute two sectors of a common circular section cylinder forming the coupling member 6. The cylindrical external faces 36 of the branches 34 are coaxial and smooth. They can include holding means 38, for example, in the form of a notch on each of the branches 34 with a flat bottom parallel to the axis 42 of the U-shaped opening 32. The notches 38 are symmetrical mirror images of each other with respect to the median plane of the U-shaped opening 32. The cylindrical inside faces 28 of the branches are coaxial and threaded. Their thread is adapted to cooperate with that of the locking member 26. The two threads 26 and 28 are complementary and are referred to as "Christmas tree" threads. The thread 28 has a first face 80 substantially perpendicular to the axis of the thread, a second face 81 substantially parallel to the axis of the thread delimiting the bottom of the thread, a third face 83 opposite the first face 80 and which can be inclined in the direction of the axis relative to the direction of the first face 80, and a fourth face 82 substantially parallel to the axis of the thread delimiting the crest of the thread. The thread 26 is substantially complementary to the thread 28. The thread 26 has a first face 90 parallel to and complementary to the face 80, a second face 91 substantially parallel to the axis of the thread delimiting the crest of the thread, a third face 93 substantially parallel to and complementary

to the face 83, and a fourth face 92 substantially parallel to the axis of the thread delimiting the bottom of the thread. During clamping, the face 90 of the thread 28 comes into contact with the face 80 of the thread 26. The reaction force  $F_r$  generated in this way has a normal component  $F_n$  parallel to the axis of the threads and a transverse component  $F_s$  in the radial direction. The transverse component  $F_s$  could cause the branches 34 to spread during tightening of the locking member 8, but the particular shape of the threads 26, 28 previously referred to reduces the transverse component  $F_s$  and therefore reduces the spreading of the branches 34 during clamping.

In a plane perpendicular to the axis 42, the bottom 40 of the U-shaped opening is semicircular to receive the connecting rod 4, with a diameter equivalent to that of the connecting rod 4. On the other hand, the bottom 40 has a concavity in the median plane of the U-shaped opening 32 with a center of curvature situated on the same side as the portion 6a of the connector 6. Finally, the bottom 40 has ends 44 parallel to the axis 42, providing a seat to receive the connecting rod 4.

The bottom portion 6b of the connector 6 includes a housing 46 opening onto the bottom face 48 at an insertion orifice 50 and opening onto the bottom 40 of the U-shaped opening 32 at a communication orifice 52. The circular section insertion orifice 50 allows the head 12 of the bone screw 2 to be inserted into the housing 46. The housing 46 has a part-spherical bottom chamber 54 adapted to receive the head 12 of the bone screw 2. The shape of the bottom chamber 54 is complementary to the spherical lateral portion 18 of the convex surface 14 of the head 12. A slot 56 crosses the bottom part 6b diametrically. The slot 56 is perpendicular to the axis 42 of the U-shaped opening 32. It extends downward as far as the bottom face 48 of the connector 6 and upward until it opens onto the bottom 40 of



the U-shaped opening 32. Thus the bottom part 6b is divided into two subparts 58 and 60 which are symmetrical mirror images of each other with respect to the median plane of the slot 56. The slot 56 facilitates clipping the head 12 into the coupling member 6 by facilitating deformation of the receiving space 46.

Prior to the procedure, each connector 6 is premounted by clipping it onto the head 12 of the bone screw 2. The bone screw is implanted in the patient using an instrument inserted into the operating means 24 via the communication orifice 52. When the screw 2 has been implanted, the connector 6 is free to rotate relative to the screw 2. The connector and the screw are connected together by a ball-and-socket connection formed by the head 12 and the bottom chamber 54. The rod 4 is fitted into the U-shaped opening 32 so that it rests on the ends 44 of the bottom 40. The locking member 8 is then engaged between the branches 34 of the opening 32 with the threads 26 and 28 interengaged with each other. The locking member 8 is then pressed against the rod 4 and the surgeon tightens the locking member 8. The locking member 8 bears on the rod 4. The rod 4 bears on the ends 44 of the bottom 40, which is then deformed because of the presence of the slot 56 perpendicular to the axis 42 of the opening 32, which is closed up as the two subparts 58 and 60 move toward each other. Consequently, the receiving space 46 and the chamber 54 are closed up onto the head 12 of the bone screw 2, locking the assembly in position, rigidly immobilizing the connector on the head of the bone screw.

In the second embodiment, shown in figure 7, the modifications relative to the first embodiment relate to the bottom part of the connector 106. The housing 146 no longer includes a spherical chamber, but is in the shape of a circular cylinder with two flats 102 and 104. The radius of the circular portion 108 can be equivalent to the radius

of the head 12 of the bone screw 2. The two flats 102 and 104 are parallel to the slot 56. A circular section hole 110 perpendicular to the flats 102 and 104 passes completely and diametrically through the bottom part in the area of the flats and perpendicularly thereto. The diameter of the hole 110 is substantially equivalent to the width of the flats 102 and 104.

When the connector 106 is clipped to the head 12 of the bone screw 2, the head 12 locates in the holes 110, leaving free the ball-and-socket connection formed in this way.

The use of this embodiment is identical to that of the first embodiment during clamping, the deformation of the receiving space 146 by the movement toward each other of the two subparts 158 and 160 obliging the two flats 102 and 104 to move toward each other, thereby immobilizing the head 12 of the bone screw 2 in the holes 110.

In the third embodiment, shown in figure 8, the modifications relative to the previous embodiment relate to the bottom part of the connector 206. The housing 246 and the slot 256 are coincident, the slot 256 being the same width as the housing 246. The width L of the slot 256 is less than the diameter of the head 12 of the bone screw 2. As in the preceding embodiment, a circular section hole 210 passes completely through the bottom part of the connector 206 in the area of the flats and perpendicularly thereto, diametrically and perpendicularly to the walls of the slot 256. The diameter of the hole 210 is less than that of the spherical part 18 of the convex surface 14 of the head 12.

The clipping is effected in the same manner: the head 12 is accommodated in the holes 210, leaving free the ball-and-socket connection formed in this way.

The use of this embodiment is identical to that of the second embodiment. The locking in position is similar.

Of course, many modifications can be made to the

invention without departing from the scope of the invention.

The anchor members can be hooks. The clamping means can include a ring or a flange adapted to be threaded over the branches of the U-shaped opening instead of or in addition to the locking member. In the latter case, the flange or ring can be connected to the locking member.

The thread cooperating with that of the branches  
can be on the flank, the branches being threaded on their  
10 outside face.

CLAIMS

1. A multiaxial connection osteosynthesis system,  
in particular for the spine, including a bone anchor member  
5 (2) having a head (12), a connecting member (4), a  
connector (6; 106; 206) having a first deformable housing  
(46; 146; 246) adapted to receive the head and a second  
housing (32) adapted to receive the connecting member, the  
10 system including clamping means (8) for clamping the  
connecting member in the second housing, characterized in  
that the connector is arranged so that, when the clamping  
means load the connecting member in the second housing, the  
connecting member loads the connectors directly to deform  
the first housing and immobilize the head therein.

15 2. A system according to claim 1 characterized in  
that the first housing includes a chamber (54) with a  
concave surface.

3. A system according to claim 1 or claim 2  
characterized in that the first housing includes a cavity  
20 (110; 210) adapted to receive part of the head (12).

4. A system according to any of claims 1 to 3  
characterized in that the head has a spherical part (18).

5. A system according to any of claims 1 to 4  
characterized in that the connector includes a slot (56;  
25 256) in the first housing.

6. A system according to any of claims 1 to 5  
characterized in that the first housing has a U-shaped  
opening having an axis (42) and two branches (34) at a  
distance from and facing each other.

30 7. A system according to claims 5 and 6  
characterized in that the slot is perpendicular to the axis  
(42) of the U-shaped opening.

8. A system according to claim 6 or claim 7  
characterized in that the clamping means include a locking  
35 member (8) adapted to engage between the branches of the

U-shaped opening.

9. A system according to any of claims 6 to 8 characterized in that the clamping means include a flange adapted to fit around the branches of the U-shaped opening.

5 10. A system according to any of claims 6 to 9 characterized in that the branches (34) of the U-shaped opening have a screwthread (28).

10 11. A system according to claim 10 characterized in that the screwthread (26, 28) has a face (80) substantially perpendicular to the axis of the thread and oriented in a penetration direction of the clamping means on the connector.

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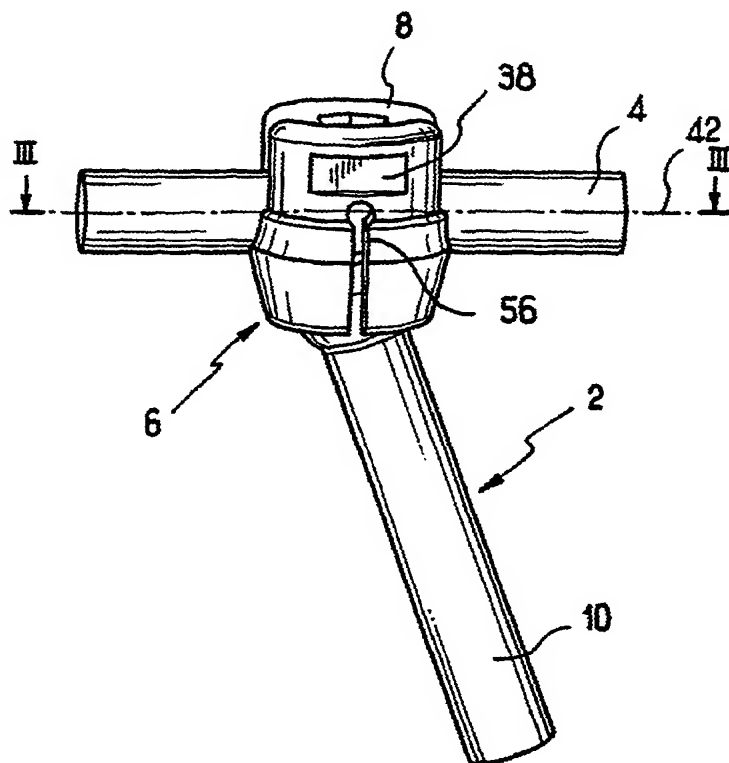
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[Suite sur la page suivante]

(54) Title: MULTIAXIAL CONNECTION FOR OSTEOSYNTHESIS

(54) Titre: LIAISON POLY-AXIALE POUR OSTEOSYNTHESE



(57) Abstract: The invention concerns a multi-axial osteosynthesis system in particular for the spine, comprising a bone anchoring element (2) comprising a head, a coupling element (4), a connector (6) having a first deformable housing for receiving the head and a second housing for receiving the coupling element, the system comprising means for clamping (8) the coupling element in the second housing, the connector being arranged such that, when the clamping means urges the coupling element into the second housing, the coupling element directly urges the connector to deform the first housing and lock the head therein.

(57) Abrégé: Le système d'ostéosynthèse à liaison poly-axiale notamment pour le rachis, comprend un élément d'ancrage osseux (2) comportant une tête, un élément de liaison (4), un connecteur (6) présentant un premier logement déformable pour recevoir la tête et un deuxième logement pour recevoir l'élément de liaison, le système comprenant un moyen de serrage (8) de l'élément de liaison dans le deuxième logement, le connecteur étant agencé de sorte que, lorsque le moyen de serrage sollicite l'élément de liaison dans

le deuxième logement, l'élément de liaison sollicite directement le connecteur pour déformer le premier logement et y bloquer la tête.

WO 01/06940 A1

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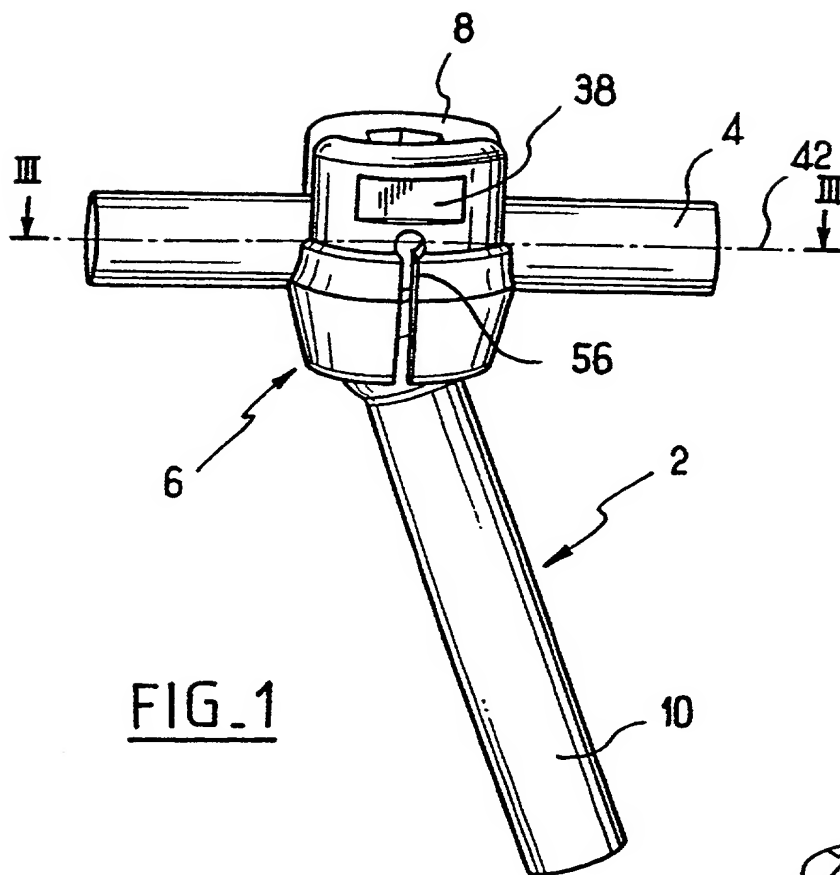


FIG. 1

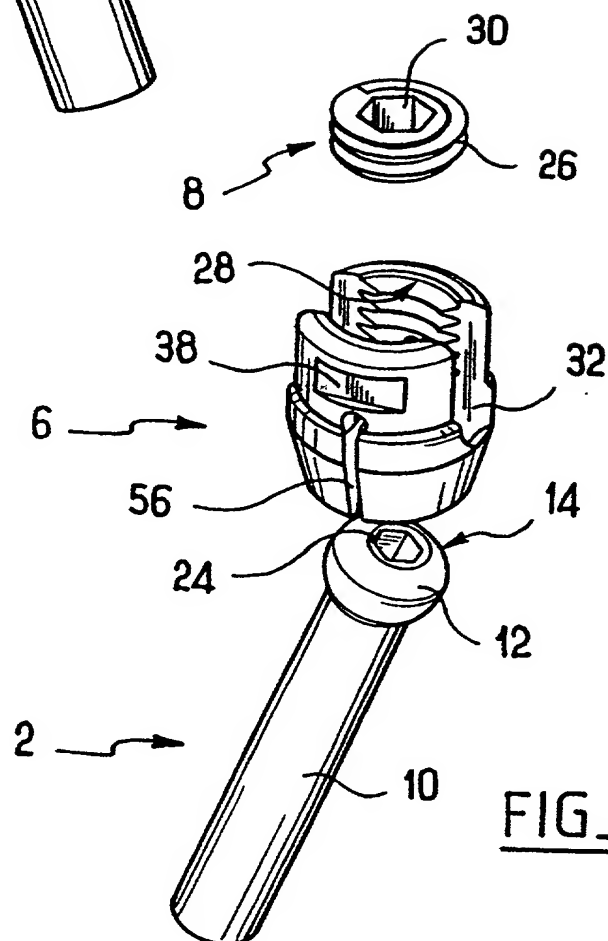


FIG. 2

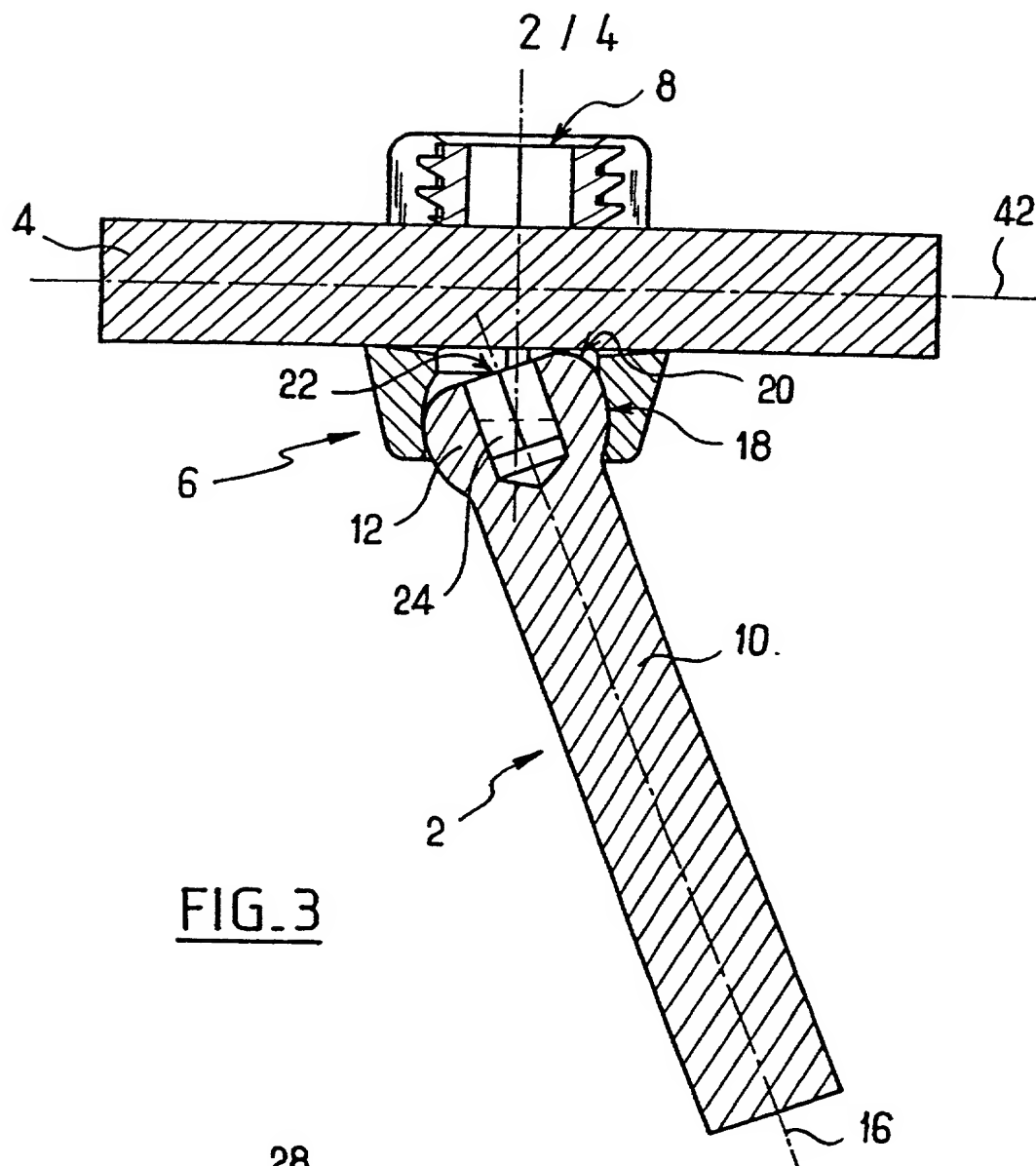


FIG. 3

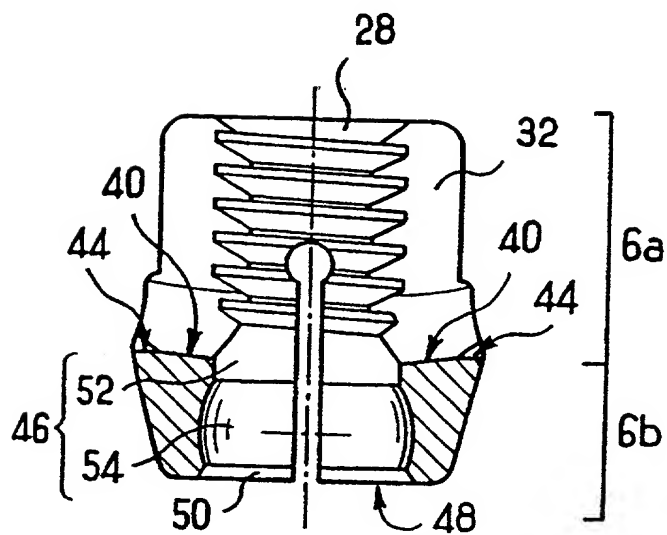


FIG. 6

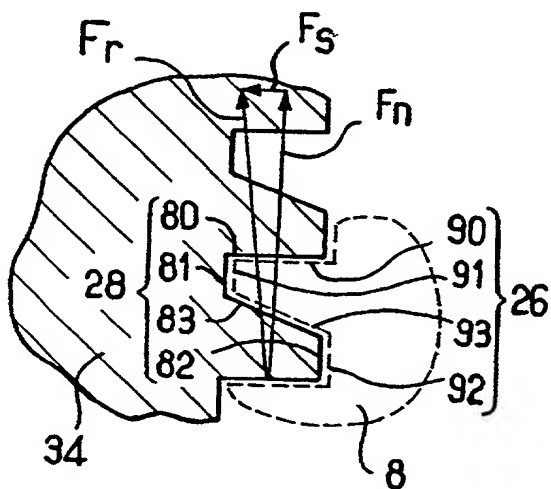
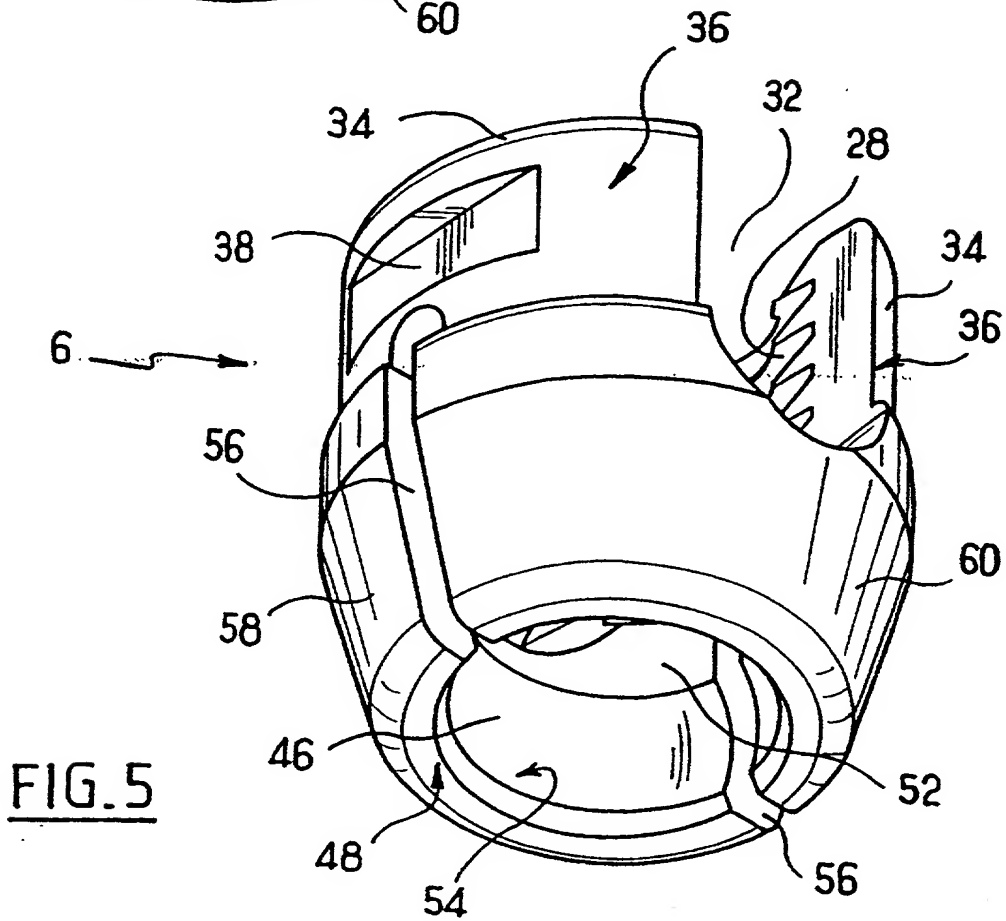
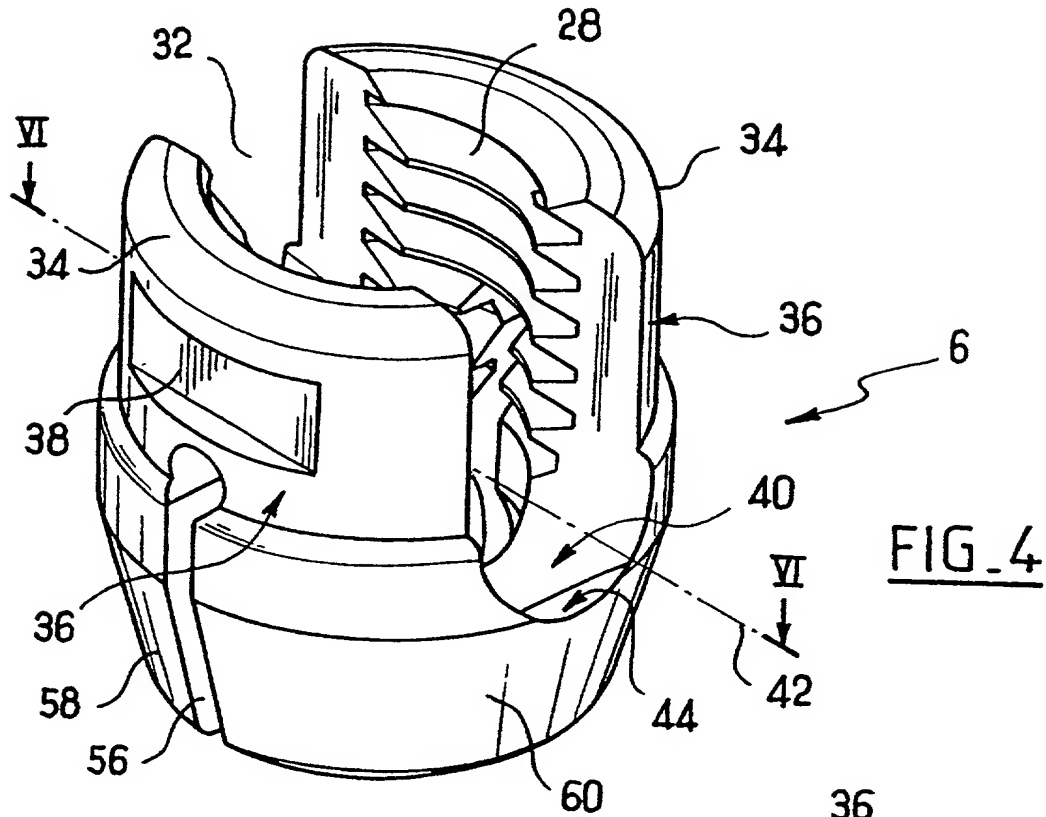


FIG. 6a



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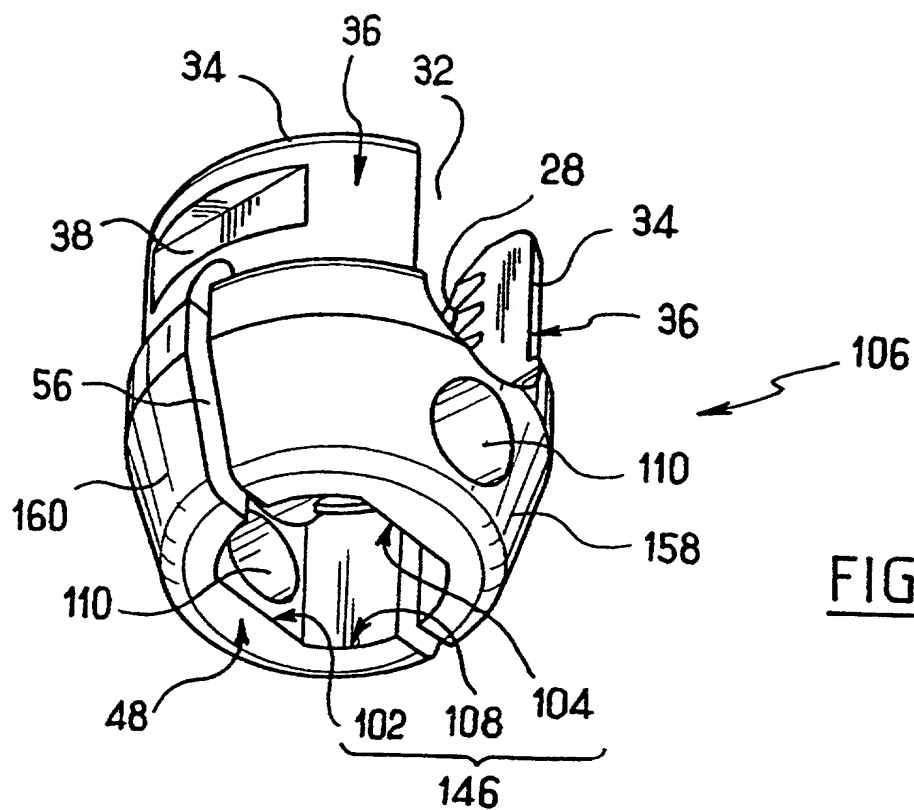


FIG. 7

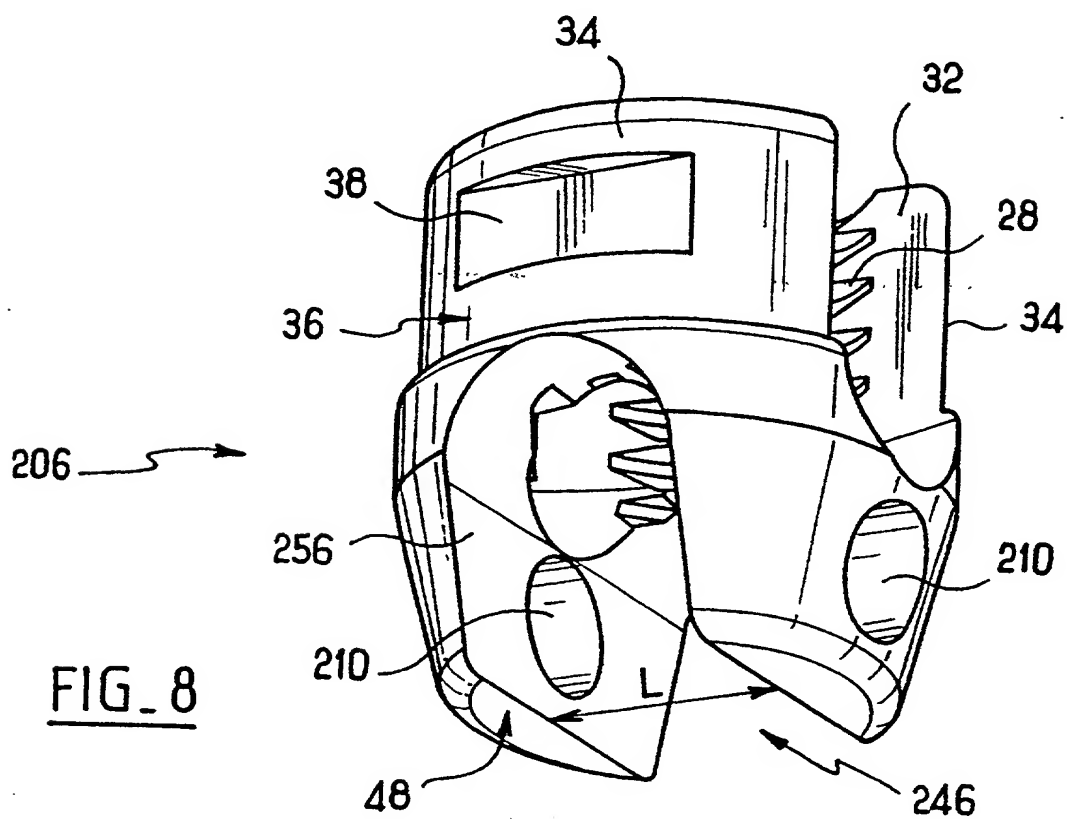


FIG. 8

# DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION

ATTORNEY'S DOCKET NO.: SPINE-400

As a below-named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: MULTIAXIAL

CONNECTION FOR OSTEOSYNTHESIS

is attached hereto

☒ was filed on 20 JULY 2000

as United States Application Number or PCT International Application Number PCT/FR00/02085 and was amended on \_\_\_\_\_ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed:

PRIOR FOREIGN APPLICATION(S)			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (month, day, year)	PRIORITY CLAIMED
FRANCE	99/09524	JULY 22, 1999	YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>
			YES <input type="checkbox"/> NO <input type="checkbox"/>
			YES <input type="checkbox"/> NO <input type="checkbox"/>

LISTING OF FOREIGN APPLICATIONS CONTINUED ON PAGE 3 HEREOF ☐ YES ☒ NO

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

Application Number: \_\_\_\_\_ Filing Date: \_\_\_\_\_

Application Number: \_\_\_\_\_ Filing Date: \_\_\_\_\_

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s), or § 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

U.S. Parent Application Serial Number: \_\_\_\_\_ Parent Filing Date: \_\_\_\_\_ Parent Patent No.: \_\_\_\_\_

U.S. Parent Application Serial Number: \_\_\_\_\_ Parent Filing Date: \_\_\_\_\_ Parent Patent No.: \_\_\_\_\_

PCT Parent Number: \_\_\_\_\_ Parent Filing Date: \_\_\_\_\_

LISTING OF US APPLICATIONS CONTINUED ON PAGE 3 HEREOF: ☐ YES ☒ NO

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

30  
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## DECLARATION -- Page 2

ATTORNEY DOCKET NO. SPINE-400

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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